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ZHONG LUN

IP Protection in Cross-Border Biotech Investments

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Bar Admission

PRC and New York State
Chinese Patent Bar

Education

LL.M., Stanford Law School
LL.M, East China University of Politics and Law
Master of Science, China Academy of Medical
Sciences
Bachelor of Science, Lanzhou University

Languages

Chinese and English

Practice Areas

Healthcare & Life Sciences, Intellectual Property, Dispute Resolution

Personal Honors

- 2015-2020 Leading Lawyer for Healthcare by Chambers Asia Pacific
- 2014-2020 Leading Lawyer for IP Litigation by Chambers Asia Pacific
- 2018-2020 Highly Recommended Lawyer for healthcare by Legal 500
- 2016-2020 IAM Patent 1000 - The World's Leading Patent Professionals by Intellectual Asset Management
- 2016 China Top 15 IP Lawyers by Asian Legal Business
- 2014 Outstanding Young Partner by Chambers Asia Pacific

Professional Memberships

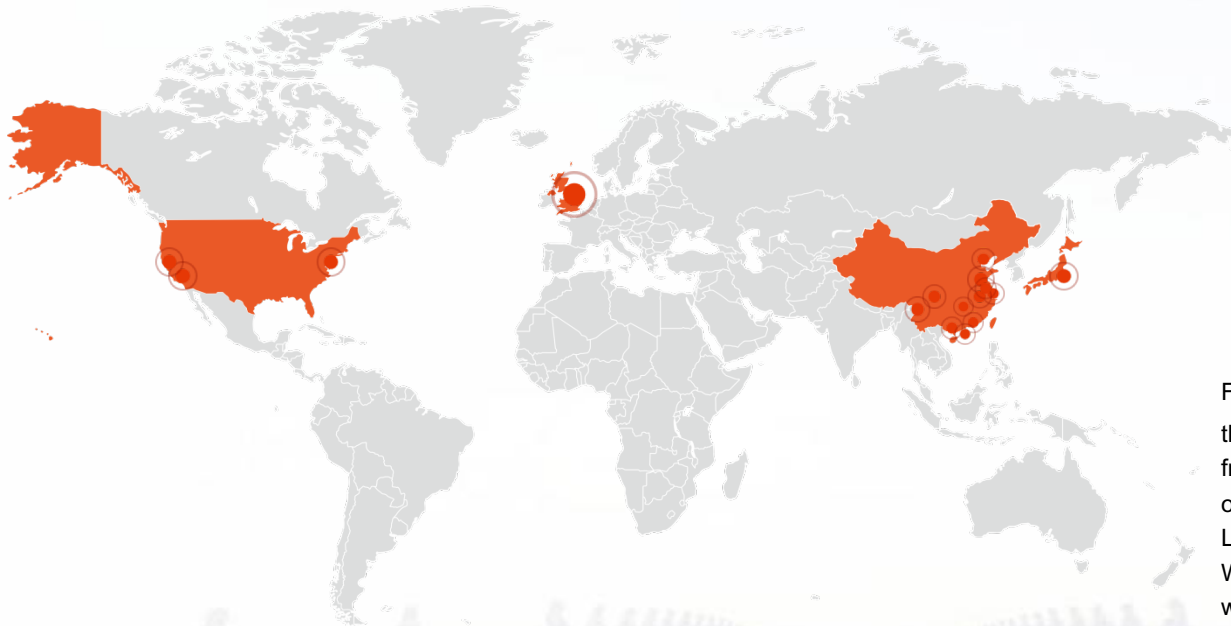
- American Bar Association (ABA)
- All China Lawyers Association (ACLA)
- All China Patent Agents Association (ACPAA)
- International Trademark Association (INTA)
- International Association for the Protection of Intellectual Property (AIPPI)

Publications (part)

- *Remdesivir was preemptively registered? Eight questions about drug patents*, Zhong Lun Review, February 2020.
- *Transformation and transcendence: From "generic drugs" to "original patented drugs"*, LexisNexis, December 2019; Zhong Lun Review, January 2020.
- *Trends and Developments in Life Science 2019 in China*, Chambers and Partners (Life Science practice guide), January 2019.
- *Trends and Developments in Pharmaceutical Advertising 2019 in China*, Chambers and Partners (Pharmaceutical Advertising practice guide), January 2019.
- *Trends and Developments in the Compliance Regulations of Healthcare Big Data Industry*, LexisNexis, December 2018; Zhong Lun Review, December 2018.

Strictly Confidential

Legal Solutions For China Business



18 Offices

Founded in **1993**, Zhong Lun Law Firm was one of the first private law partnerships to receive approval from the justice administration department. After years of rapid development and steady growth, today Zhong Lun is one of the largest full service law firms in China. With over 310 partners and over 2100 professionals working in eighteen offices in Beijing, Shanghai, Shenzhen, Guangzhou, Wuhan, Chengdu, Chongqing, Qingdao, Hangzhou, Nanjing, Hainan, Tokyo, Hong Kong, London, New York, Los Angeles, San Francisco and Almaty.

Zhong Lun offers high-quality Chinese legal services across a wide range of industries and sectors by dint of our specialized expertise and close teamwork.

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Our Professionals

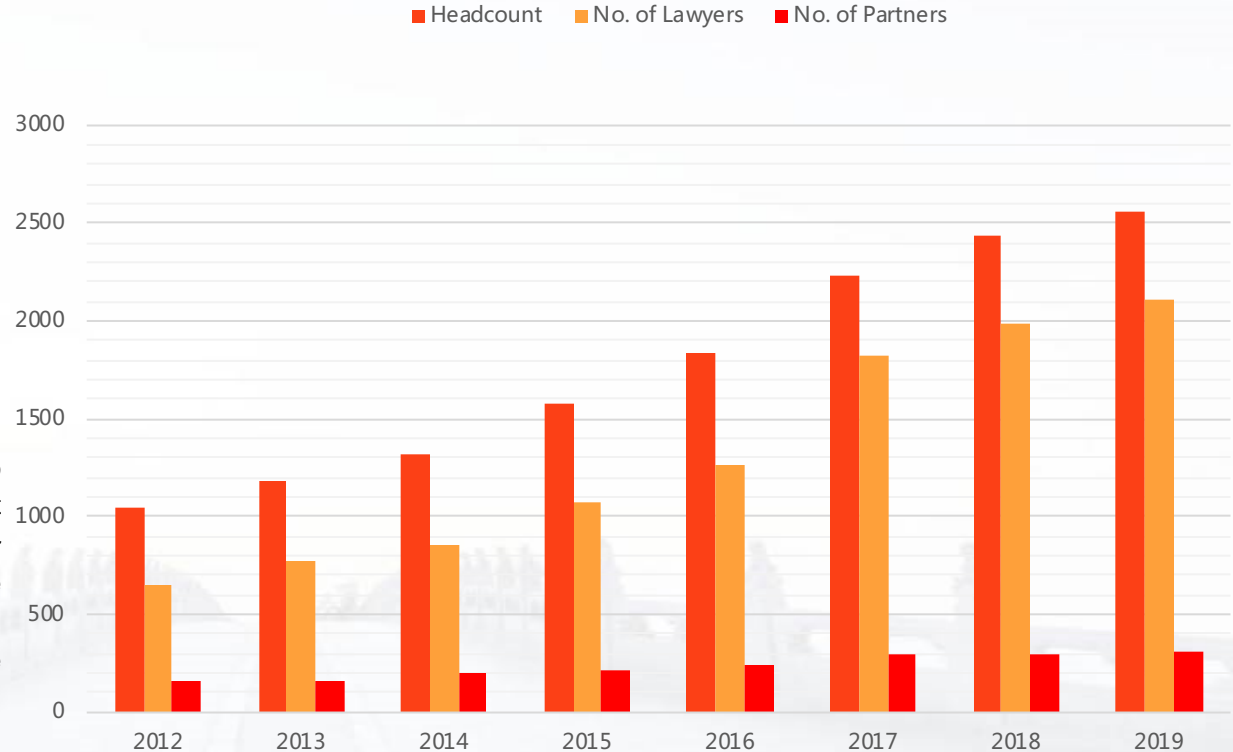
Our success to date is attributable to our intellectual agility.

320+ Partners

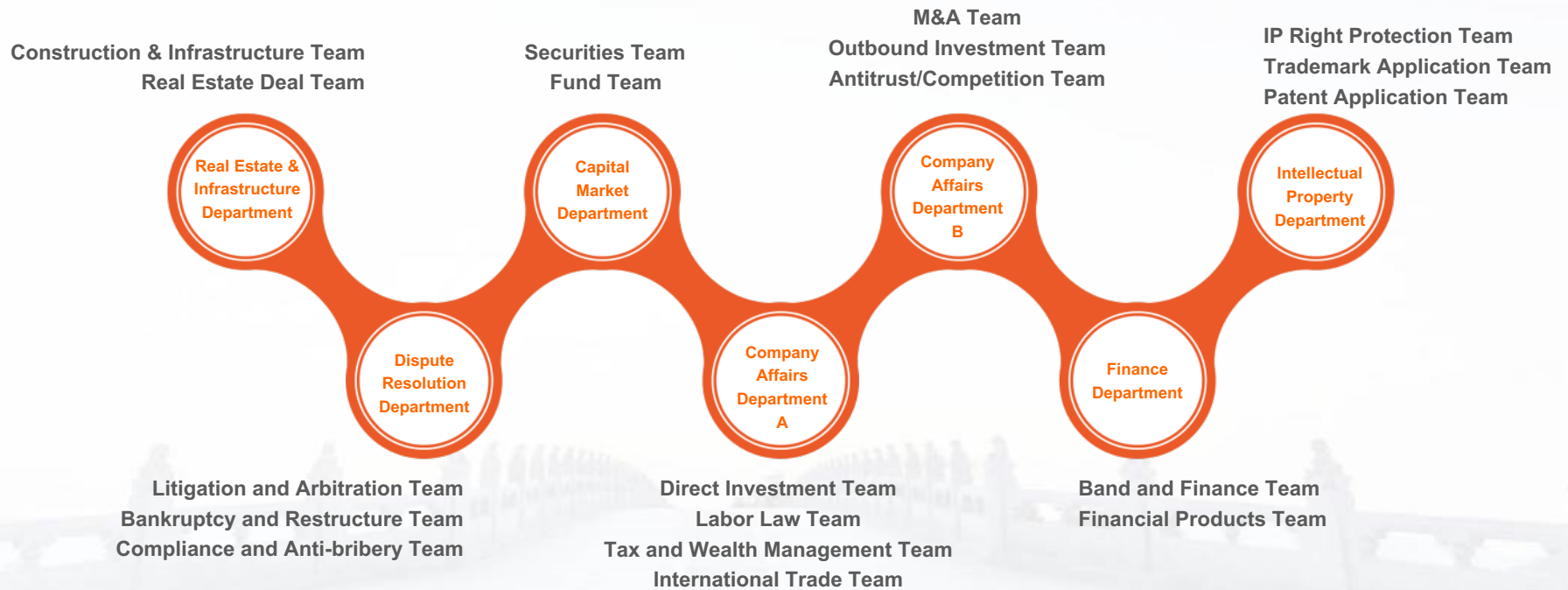
2100+ Professionals

2500+ Employees

By practicing at the highest levels of the legal profession in a culture that emphasizes collegiality, team work, respect for everyone, professional and business ethics, and duty to our communities, we attract and retain the best professionals to ensure the best outcomes for our clients. Most of our professionals have graduated from prestigious law schools in China and abroad. Many of them have practiced in leading international law firms. All of our partners are successful practitioners in their fields with extensive practice experience and in-depth knowledge of the clients' business.



Business Departments



Our Honors

We have the most practice areas recommended by *Chambers Asia Pacific* for many consecutive years
 We have the most practice areas rated Band 1 by *Chambers Asia Pacific* for many consecutive years
 We have the largest number of lawyers recommended by *Chambers Asia Pacific* for many consecutive years

Time	Practice areas ranked in band 1	Total practice areas ranked	Partners rated as leading lawyers
2020	17	30	66
2019	17	28	61
2018	18	28	57
2017	17	27	52
2016	17	27	48
2015	16	23	45
2014	16	23	48

Consistently Ranked in the Top Tier in China



CHAMBERS

2017&2019
 “PRC Law Firm of the Year
 (Dispute Resolution)”
 2015
 PRC Law Firm of the Year
 (Corporate and Finance)



IFLR

2015 & 2017
 “National Law Firm
 of the Year”



ALB

2015-2016
 One of the Most 10
 Powerful Law Firms in China
 2013 & 2014 & 2016
 “China Employer of Choice”



The Lawyer

2016
 “Law firm of
 the Year: Asia”



CLP

2016
 “China Firm of the Year”
 “Pro Bono Initiatives
 of the Year”



CBLJ

2013 - 201
 “Best Overall PRC Law Firm”
 2014 - 2019
 “Law Firm of the Year (Beijing) ”

CATALOG

PART 1 | Importance of IP in Biotech Investment

PART 2 | Case Studies in Cross-Border Transaction

PART 3 | Patent Fight concerning Remdesivir

Importance of IP in Biotech Investment

➤ Investment in Biopharma field in China (Up to 2019.11)

- **Investment Amounts:** 21.738 billion (RMB) (Reduced 45%)
- **Investment Events:** 253

➤ Investment Trends

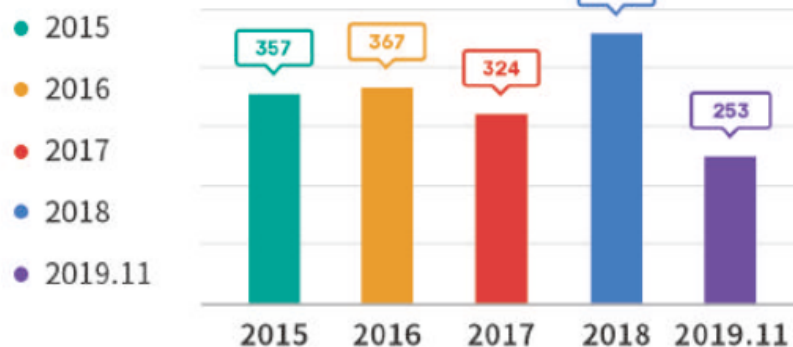
- More rational
- Still in high demand

发生金额 (亿元)



数据来源: 赛迪生物医药产业大脑, 2019.12

事件数 (起)



数据来源: 赛迪生物医药产业大脑, 2019.12

Importance of IP in Biotech Investment



Importance of IP in Biotech Investment

➤ What is patent?



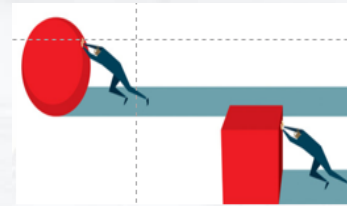
- A form of intellectual property giving its owner the right to exclude others from implementing the invention for a period of time

➤ What's the function of patent system?

- *"Patent system is to add the oil of interest to the fire of genius"*
- Abraham Lincoln

➤ Why patent is important for Biotech Industry?

- *Market competition advantage brought by exclusivity*



Importance of IP in Biotech Investment

- **No infringement risk if there is a patent?** **NO.**
 - **Nature of patent right:** not confer the right to implementing patented invention.
 - **Two scenarios:**
 - ✓ patented invention is the improvement of others' patented technology
 - ✓ only layout primary patent

- **No infringement risk if an invention is self-developed?** **NO.**
 - **Determination of patent infringement:** all elements rule; irrelevant with whether independently developed or not

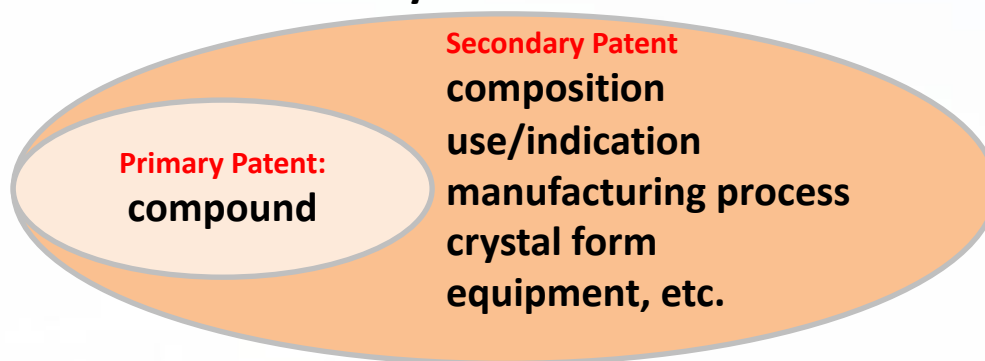
- **Is There an International Patent?** **NO.**
 - Patent is territorial
 - PCT application
 - ✓ often referred to as “international patent”;
 - ✓ unexamined patent application at the international phase of PCT

Importance of IP in Biotech Investment

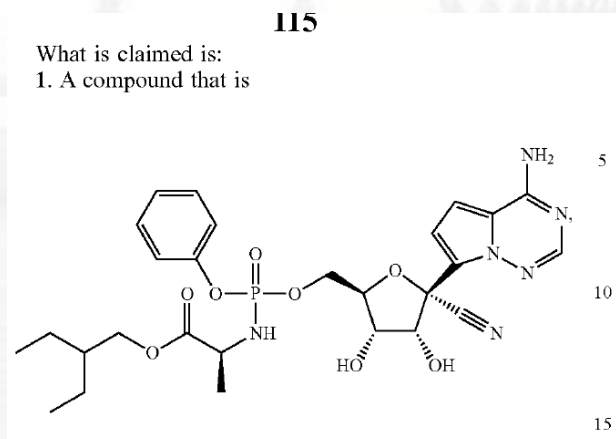
➤ Patented Products = Good Products?

NO.

- **Patent Types** : invention, utility model and design
 - ✓ Utility model and design require no substantial examination
- **Primary Patent and Secondary Patent:**

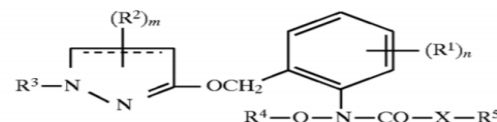


- **Scope of Protection:** the claims.



VS

1. A 2-[(dihydro)pyrazol-3'-yloxymethylene]anilide of the formula I



where -- is a single or double bond and the indices and the substituents have the following meanings:

- n is 0, 1, 2, 3 or 4, it being possible for the substituents R^1 to be different if n is greater than 1;
- m is 0, 1 or 2, it being possible for the substituents R^2 to be different if m is greater than 1;
- X is a direct bond, O or NR^a ;
- R^a is hydrogen, alkyl, alkenyl, alkynyl, cycloalkyl or cycloalkenyl;
- R^1 is nitro, cyano, halogen, unsubstituted or substituted alkyl, alkenyl, alkynyl, alkoxy, alkenyloxy, alkynyloxy or in the case where n is 2, additionally is an unsubstituted or substituted bridge bonded to two adjacent ring

markush
claim

CATALOG

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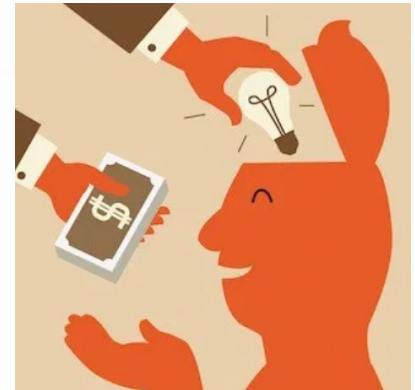
Case Studies in Cross-Border Transaction

➤ License Grant

- **License Activities:** manufacture, use, sell, offering to sell, import
- **License Type:** ordinary license, sole license, exclusive license
- **License Territory**
- **License Term**

➤ Sublicense

- **Clearly Specified** in the license agreement
- **Sublicense Scope:** not exceeding License Scope, otherwise may be invalid or constitute infringement



Case Studies in Cross-Border Transaction

➤ Ownership to Improved Technology:

- **Article 354 of Contract Law:**
 - ✓ depending on agreement;
 - ✓ in case of no agreement, belonging to the party that makes the improvements.
- **Regulations on the administration of technology import and export(Revised in 2019):**
 - ✓ original stipulation “improved technology belongs to party that makes the improvements within the validity period of technology import contract” **was deleted**

Case Studies in Cross-Border Transaction

➤ Representations and Warranties:

- Not infringing others' IP within the License Territory
- Response to infringement charges

➤ Dispute Resolution

- Litigation or arbitration
- Applicable law
- Competent court



Foreign arbitration awards, foreign court judgments and rulings may not be recognized and enforced in China

CATALOG

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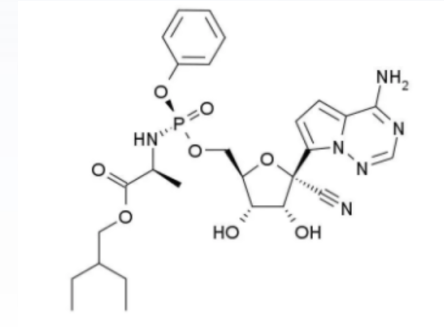
PART 2 | Case Studies in Cross-Border Transaction

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Patent Fight concerning Remdesivir

➤ Basic Info Concerning Remdesivir

- Nucleotide analog with broad-spectrum antiviral activity
- Developed by Gilead Sciences
- Originally to treat Ebola, SARS, MERS
- Not licensed or approved anywhere



➤ Is Remdesivir Protected by Patents in China?

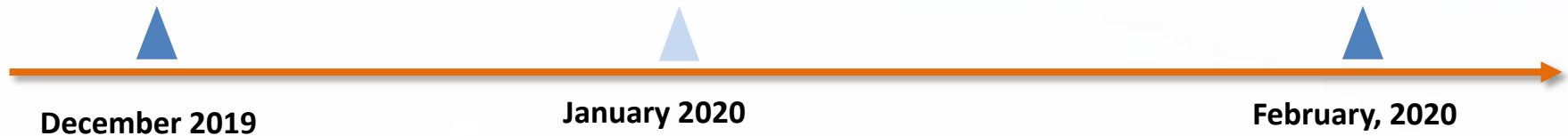
No.	Publication No.	Status
1	CN103052631B	GRANTED
2	CN105343098B	
3	CN107074902A	PENDING
4	CN107073005A	
5	CN108348526A	
6	CN110636884A	

- Filed by Gilead Sciences
- Relating to compound, composition, use/indication, manufacturing process, crystal form of Remdesivir
- **CN108348526A** relates to use of Remdesivir in **treating coronavirus**

Patent Fight concerning Remdesivir

➤ Patent Fights Timeline

- One US hospital tried to treat 2019-nCoV with Remdesivir
- Wuhan Institute Of Virology: a patent application relating to Remdesivir was filed on January 26, 2020
- 2019-nCoV found in Wuhan



➤ Can Wuhan Institute Of Virology File Application Relating to Remdesivir?

- **One drug** can have **multiple patents**: primary patents and secondary patents
- Wuhan Institute Of Virology's patent application: secondary patent application (**use of Remdesivir in treating 2019-nCoV**)

并能够完全实现自主供应的药物磷酸氯喹，不申请相关专利，以鼓励相关企业参与疫情防控的积极性；对在我国尚未上市，且具有知识产权壁垒的药物瑞得西韦，我们依据国际惯例，从保护国家利益的角度出发，在1月21日申报了中国发明专利（抗2019新型冠状病毒的用途）并将通过PCT（专利合作协定）途径进入全球主要国家。如果国外相关企业有意向为我国疫情防控做出贡献，我们双方一致同意在国家需要的情况下，暂不要求实施专利

- No prohibitions on the applicant of secondary patent

Patent Fight concerning Remdesivir

➤ Will Wuhan Institute Of Virology's Application Be Granted?

- **Requirements:**

- ✓ Novelty:

- new use substantially different from original known use
 - new use not directly revealed by the mechanism and pharmacological action of original known use
 - new use not belongs to upper concept of original known use
 - characteristics related to use have a limited effect on the pharmaceutical process

- ✓ Inventive step:

- unexpected technical effect: needed to be proved by experimental data.
 - application filed on January 26, 2020
 - clinical trials in China launched on February 4, 2020
 - supplementary experimental data can be submitted

- ✓ Practicality

- **Not published yet**

Thank You

For More Info, Please Contact

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ZHONG LUN LAW FIRM

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